Susan M. Cooper PO Box 3552 Camarillo, CA 93011 3588 '99 JUN 16 A10:03(805) 383-0760

June 6, 1999

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re: 99P-1340/CP 1 Petition to Have "Eternity eau de parfum" Misbranded

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning—The safety of this product has not been determined."

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may effect the health of many people, including: people with asthma, reactive airways disease, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers.

99P-1340

0120

When I am exposed to certain fragrance products, such as "Eternity," I experience sudden, painfully sharp headaches, loss of concentration, unusual tiredness and lethargy, foggy thinking, irritability, tingling sensation on my scalp, increased nasal and chest mucus, coughing, burning eyes and nasal passageways, and bronchoconstriction resulting in decreased peak expiratory flow values (exacerbation of my asthma) requiring use of my rescue inhaler, which lasts anywhere from several hours to 3 or 4 days, depending on the product, proximity, and length of exposure. I have had to purchase a special air purifier which rids the air of volatile organic compounds in order to function at work where people around me wear various perfumes includning "Eternity." I have had to stop attending my church because of the abundance of perfumes there. All this occurs despite my taking 7 to 9 medications daily to control my allergies and asthma.

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals in fragrances have already ruined countless lives and severely limited the activities of others.

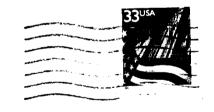
Thank you.

Susan Cooper

Gusan Cooper







Dookets Mgmf. Branch FDA DHHS, Rm. 1-23 12420 Parklawn Dr. Rockville, MD 20857